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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/654,980	09/05/2003	Rajiv Gupta	033018-113	5640
21839	7590	12/23/2004	EXAMINER	
BURNS DOANE SWECKER & MATHIS L L P POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			RAGONESE, ANDREA M	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/654,980

Applicant(s)

GUPTA ET AL.

Examiner

Andrea M. Ragonese

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19-28, 32-34 and 41-48 is/are pending in the application.
- 4a) Of the above claim(s) 41-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-28 and 32-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/24/04; 9/20/04.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Response to Amendment*

1. The amendment filed on September 20, 2004 has been entered. Examiner acknowledges that **claims 19, 21, 23, 27 and 34** have been amended, **claims 1-18, 29-31 and 35-40** have been canceled and **claims 41-48** have been added.

### *Election/Restrictions*

2. Newly submitted **claims 41-48** are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the method is a independent and distinct species in which the *aerosol is mixed with entrainment air* at a location outside the aerosol confinement sleeve and within a mouthpiece.

3. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, **claims 41-48** are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### *Response to Arguments*

4. Applicant's arguments, regarding **claims 19-28 and 32-34**, filed on September 20, 2004, have been fully considered but they are not persuasive because the method steps claimed are inherent in the use of the apparatus through which the method is performed. For more support, please see rejections below. Therefore, the rejections of the previous Office action are reiterated hereinafter and are hereby made FINAL.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. **Claims 21** and **41-48** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Regarding **claim 21**, the ranges of values of the mass median aerosol diameter was not disclosed in the original disclosure of the instant application; and thus, is considered new matter and must be canceled from the claims. Regarding **claims 41-48**, the method of generating an aerosol in which the aerosol is mixed with entrainment air at a location outside of the aerosol confinement sleeve was not disclosed in the original disclosure of the instant application; and thus, is considered new matter and must be canceled from the claims.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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8. **Claims 19-22, 24-27 and 32-33** are rejected under 35 U.S.C. 102(b) as being anticipated by Howell et al. (US 5,743,251). Howell et al. discloses a method for generating an aerosol, inherent in the use of the apparatus as shown in Figure 1, comprising the steps of: supplying liquid from source **33** to a flow passage **23** having an outlet end **25** (column 3, lines 2-5); heating the liquid with heater **27** so as to volatilize liquid in the flow passage **23** (column 3, lines 5-20); directing the volatilized liquid out of the outlet end **25** of the flow passage **23** into an aerosol confinement sleeve—broadly interpreted to be the mouthpiece **39** (shown by dotted lines in Figure 1)—located at the outlet end **25** of the flow passage (column 3, lines 20-22 and column 6, lines 9-23); and admixing the volatilized liquid with air to produce an aerosol (column 3, lines 22-24 and column 6, lines 32-47). Based on the manufacturing of an aerosol generator device, it would be inherent in the design and production of such a device to produce one in which the confinement sleeve length and/or transverse dimension are designed to achieve the desired aerosol particles through the use of a device. Therefore, as broadly and reasonably interpreted, the prior art of record still anticipates the claimed invention. As for the mouthpiece dimensions, “the mouthpiece is approximately 1 inch in diameter and between 1.5 and 2 inches in length”, which falls well within the claimed ranges and ratios (column 6, lines 33-47). The device is fully capable of producing aerosol particles with an MMAD of less than 2 microns, which is well within the claimed ranges and ratios (column 9, lines 9-18).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. **Claims 23, 28 and 34** are rejected under 35 U.S.C. 103(a) as being unpatentable over Howell et al. (US 5,743,251) in view of Armer et al. (US 5,954,047). As previously discussed, discloses a method for generating an aerosol, inherent in the use of the apparatus as shown in Figure 1, comprising all the limitations recited in **claims 23, 28 and 34**, with the exception of use of a removably attached confinement sleeve, dispensing specific medicaments and constructing the inhaler of a specific body structure. However, the use of a metered dose inhaler with this specific body structure with a removable confinement sleeve that discharges anti-inflammatory medication was known at the time the invention was made. Specifically, Armer et al. teaches the use of

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a metered dose inhaler **10** with a removable mouthpiece **56** for dispensing medication for therapeutic treatment of the lungs (column 1, lines 10-20), as shown in Figure 1. Regarding **claim 23**, the mouthpiece **56** is broadly interpreted to be the confinement sleeve of the present invention and is removable from the inhaler **10** since the inhaler **10** and mouthpiece **56** are constructed separately (column 8, lines 6-20). Regarding **claim 28**, the medicaments that are dispensed by the inhaler are anti-inflammatory agents, such as corticosteroids (column 1, lines 11-14). Regarding **claim 34**, the inhaler **10** has a body **64** that surrounds a portion of the flow passage **41** and has an inner diameter, which is equal to the inner diameter of a portion of the mouthpiece **56**, as shown in Figures 1-2. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Howell et al. by altering the metered dose inhaler of the prior art to have a body structure with an inner diameter equal to that of the confinement sleeve and a removable mouthpiece and to dispense anti-inflammatory medicaments because it is well known in the art, as taught by Armer et al., to dispense anti-inflammatory agents through a metered dose inhaler with a body of equal diameter of a confinement sleeve in order to dispense the medication and to use a removable confinement sleeve so that different patients can use the same inhaler apparatus or the confinement sleeve can be disinfected before the user dispensing the medication again.

### ***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

13. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese** whose telephone number is **571-272-4804**. The examiner can normally be reached on Monday through Friday from 8:30 am until 5:00 pm.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should



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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR

December 13, 2004



Henry Bennett  
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